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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,368	09/17/2003	Jens Ulrik Poulsen	6133.224-US	4554
7590	01/05/2009		EXAMINER	
Reza Green, Esq. Novo Nordisk Pharmaceuticals, Inc. 100 College Road West Princeton, NJ 08540			LUBIN, VALERIE	
			ART UNIT	PAPER NUMBER
			3626	
			MAIL DATE	DELIVERY MODE
			01/05/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/664,368	POULSEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	VALERIE LUBIN	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 17 September 2003.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-9 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-9 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 17 September 2008 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/20/03</u> .  | 6) <input type="checkbox"/> Other: _____ .                        |

**DETAILED ACTION**

***Acknowledgements***

1. Claims 1-9 are pending

For reference purposes, the document paper number is 20081224

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 1 is directed to a system comprising an insulin delivery unit, a blood glucose monitor and a processor. However, the last limitation of the claim recites a method step of transmitting data to the insulin delivery unit. The claim is unclear, as it is directed to both a system and a method.

Claims 2-9 are rejected under the above analysis as they recite limitations directed to both a system and method steps.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castellano et al. U.S. Patent No. 5,536,249.

7. With respect to claim 1, Castellano recites a system comprising and insulin delivery unit (Col. 5 lines 25-26); a blood glucose monitor (Col. 5 lines 26-28); and a master module including a processor (Col. 7 lines 15-21; col. 14 lines 31-39; col. 16 lines 23-28).

Castellano does not specifically recite transmitting the dose of insulin to the insulin delivery unit; however, he does disclose an I/O port capable of receiving and transmitting (Col. 14 lines 42-49). It would therefore have been obvious to one of ordinary skill in the art to combine the teachings of Castellano to not only receive data from the insulin delivery unit, but also to transmit data back to it in order to facilitate and expedite data flow.

Claims 4-6 and 9 are rejected under the analysis of claim 1.

8. Claim 2 is rejected, as Castellano recites a microprocessor receiving other data (Col. 8 lines 4-7).

9. Claim 3 is rejected as the type of data stored is non-functional descriptive material that does not further limit the system disclosed (*In re Gulack*, 217 USPQ 401 (Fed. Cir. 1983), *In re Ngai*, 70 USPQ2d (Fed. Cir. 2004), *In re Lowry*, 32 USPQ2d 1031 (Fed. Cir. 1994); MPEP 2106.01 II).

10. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castellano et al. U.S. Patent No. 5,536,249 in view of Worthington U.S. Patent No. 5,822,715.

11. For claim 7, Castellano recites a system comprising an input means for receiving data about a subject (Col. 6 lines 24-26); a proposal generator for proposing one or more courses of treatment (Col. 14 lines 42-49). Castellano does not specifically recite a processor to model a human carbohydrate metabolism; however, Worthington does (Col. 6 lines 64-66; col. 14 lines 28-30). It would have been obvious to one of ordinary skill in the art to combine the teachings of Castellano and Worthington to have a processor account for carbohydrate consumption because carbohydrates also impact blood glucose.

12. For claim 8, Castellano recites administering a dose of insulin (Col. 14 lines 31-39). Castellano and Worthington do not specifically recite transmitting the dose of insulin to the insulin delivery unit; however, he does disclose an I/O port capable of receiving and transmitting (Col. 14 lines 42-49). It would therefore have been obvious to one of ordinary skill in the art to combine the teachings of Castellano to not only receive data from the insulin delivery unit, but also to transmit data back to it in order to facilitate and expedite data flow.

***Conclusion***

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE LUBIN whose telephone number is (571)270-5295. The examiner can normally be reached on Monday-Friday 7:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher L. Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VL

/C Luke Gilligan/  
Supervisory Patent Examiner, Art Unit 3626